



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,644	01/08/2002	Jacques F. Banchereau	112917-143	7691

28089 7590 03/18/2005

WILMER CUTLER PICKERING HALE AND DORR LLP
399 PARK AVENUE
NEW YORK, NY 10022

EXAMINER

CHANDRA, GYAN

ART UNIT	PAPER NUMBER
----------	--------------

1646

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,644

Applicant(s)

BANCHEREAU ET AL.

Examiner

Gyan Chandra

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/12/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 53-77 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 53-68, drawn to a method of treating an autoimmune disease in a subject comprising administering an interferon antagonist, classified in class 424, subclass 85.4.
- II. Claims 69-77, drawn to a method of treating an autoimmune disease in a subject comprising administering a Flt3L antagonist wherein the antagonist is an antibody that specifically binds Flt3L or an antigen, classified in class 424, subclass 130.1.
- III. Claims 69-77, drawn to a method of treating an autoimmune disease in a subject comprising administering a Flt3L antagonist wherein the antagonist wherein the antagonist is an organic molecule, classified in class 514, subclass 1.
- IV. Claims 69-77, drawn to a method of treating an autoimmune disease in a subject comprising administering a Flt3L antagonist wherein the antagonist wherein the antagonist is a nucleic acid, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1646

Inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of treating an autoimmune disease in a subject comprising administering an interferon antagonist (Group I), the method of treating an autoimmune disease in a subject comprising administering an antibody that binds Flt3L or an antigen (Group II), the method of treating an autoimmune disease in a subject comprising administering an organic molecule (Group III), and the method of treating an autoimmune disease in a subject comprising administering a nucleic acid (Group V) are unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Each invention performs this function using a functionally divergent material.

Furthermore, the inventions of Groups I, II, III and IV require separate, distinct and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups I, II, III and IV together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and separate search requirements, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Art Unit: 1646

A. An autoimmune disease is selected from:

- i) acquired immune deficiency syndrome (AIDS)
- ii) ankylosing spondylitis
- iii) arthritis
- iv) aplastic anemia
- v) Behcet's disease
- vi) diabetes
- vii) graft-versus-host disease
- viii) Graves' disease
- ix) hemolytic anemia
- x) hypogammaglobulinemia
- xi) hyper IgE syndrome
- xii) idiopathic thrombocytopenia purpura (ITP)
- xiii) multiple sclerosis (MS)
- xiv) Myasthenia gravis
- xv) psoriasis
- xvi) lupus
- xvii) systemic lupus erythematosus (SLE)
- xviii) drug-induced lupus
- xix) diabetes melitus
- xx) Type I diabetes
- xxi) Type II diabetes

- xxii) juvenile on-set diabetes
- xxiii) rheumatoid arthritis
- xxiv) juvenile rheumatoid arthritis
- xxv) psoriatic arthritis

Claims 53 and 69 are generic to a plurality of disclosed patentably distinct species comprising an autoimmune disease. Each disease is considered to constitute a patentably distinct species because they have separate disease etiology, population sample makeup and require separate searches, for example NPL. Search of more than a single species would constitute an undue burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 53 and 69 are the examples of a generic claim.

B. An interferon antagonist is:

- xxvi) TNF
- xxvii) a TNF agonist
- xxviii) a TNF receptor agonist

Claim 53 is generic to a plurality of disclosed patentably distinct species comprising an interferon antagonist. Each interferon antagonist is considered to constitute a patentably distinct species because they have separate structure and function and require separate searches, for example NPL. Search of more than a single species would constitute an undue burden on the Office.

Art Unit: 1646

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 53 is an example of a generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 1646

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

If Applicant selects Group I, one species from the autoimmune disease group and one species from the interferon antagonist group must be chosen to be considered fully responsive. If Applicant selects Group II, one species from the autoimmune disease group must be chosen to be considered fully responsive.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra
AU 1646
31 January 2005

an *Ch* *C* *EW*
RECEIVED
JAN 31 2005
UNIT 1646